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K022304 1/2

510(k) Summary

General Information

Classification	Class I
Trade Name	AccuMap® Automatic Objective Perimeter
Submitter	ObjectiVision Pty Ltd Level 12 139 Macquarie St Sydney 2000 Australia 61-2-9252-9833
Contact	John Newton CEO

Intended Use

The AccuMap® perimetry system uses multifocal recordings of visual evoked potentials as a diagnostic aid in the detection of glaucoma.

Predicate Device

K983983 VERIS multifocal system Electro-Diagnostic Imaging, Inc.

Device Description

The AccuMap comprises the following components:

- Two monitors, one for displaying the stimulus and the other for displaying the input to and output from the OPERA software.
- A computer with specialized hardware and software.
- A four-channel medical amplifier.
- A specially designed headset.
- A hand-held button used by the patient for responding.

The design of the AccuMap means that all the components fit into one compact, mobile unit.

Monitors

The system includes two monitors, a 21-inch high-resolution monitor which displays the stimulus for the patient, and a touch screen which the technician uses to run the OPERA Firmware.

The stimulus is a dartboard pattern projected by the monitor for visualization by the patient.

AccuMap computer

The computer which is part of the AccuMap and which runs the OPERA Firmware is a Pentium III or better system.

Medical amplifier

The amplifier is a four-channel model and is driven by Windows-based software.

Electrode lead sockets

The electrode sockets, located behind the patient's chair, are labeled with the same bright colors as the electrode leads to make it easier to plug the leads in correctly.

Electrode cross

The ObjectiVision electrode cross holds the four bipolar electrodes used to record patient responses to the stimulus. The cross is based on a simple patented design and is easy to use. Two electrodes are positioned along the midline above and below the inion, and two additional electrodes are placed four centimeters on either side of the inion.

The holder standardizes the electrode positioning and speeds up the preparation and placement of the electrodes. The holder is easy to clean and is suitable for use on children as young as six years.

The electrode cross is lightweight and comfortable for the patient with the result that their neck muscles remain relaxed during the recording. A chin rest is not required and may, in fact, increase muscle tension. An ear clip electrode provides the earth.

Virtual keyboard

Because the AccuMap uses a touch screen there is no physical keyboard. Instead there is a virtual keyboard which displays automatically when you need to type something in. To use the keyboard, touch the appropriate key.

Hand-held button and fixation control

To help the patient concentrate on the center of the stimulus, they are asked to press a hand held button whenever they see a particular randomly generated number displayed

OPERA Firmware

The OPERA Firmware is used for recording and analysis. It generates the stimulus on the patient's monitor, performs signal extraction (cross correlation) and displays the results. The results include topographical evaluation of latency and amplitude, and are presented in a familiar format for easy interpretation. An asymmetry coefficient, unique to the AccuMap, compares right and left eyes allowing for the detection of very subtle changes.

Materials

All materials used in the manufacture of the AccuMap are suitable for this use and have been used in numerous previously cleared products.

Testing

Product testing was conducted to evaluate conformance to product specification. Testing included electrical safety and electromagnetic compatibility.

Summary of Substantial Equivalence

The AccuMap is equivalent to the predicate VERIS system. The AccuMap employs new technology to help reduce the subjectivity of the response of the patient, the method of operation and outcomes are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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ObjectiVision Pty Ltd
c/o Mr. Fred Henry, MS
Vice President, U.S. Regulatory Affairs
Omnicare Clinical Research, Inc.
630 Allendale Road
King of Prussia, Pennsylvania 19406

Re: K022304
Trade/Device Name: AccuMap® Automatic Objective Perimeter
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked response photic stimulator
Regulatory Class: II
Product Code: GWE
Dated: October 29, 2003
Received: November 3, 2003

Dear Mr. Henry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	k022304
Device Name:	AccuMap® Automatic Objective Perimeter
Indications for Use:	The AccuMap® perimetry system uses multifocal recordings of visual evoked potentials as a diagnostic aid in the detection of glaucoma.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022304

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _ (Per 21 CFR 801.109) OR Over-The-Counter Use _ (Optional Format 1-2-96)